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Filed : October 31, 2003

### REMARKS

This amendment is in response to the Office Action mailed December 13, 2004, and further to the personal interview conducted on February 16, 2005 between Examiner Jackson, Mitchell Dann and the undersigned. The Applicants would like to thank Examiner Jackson for extending the courtesy of an interview to Applicants' representatives.

Prior to entry of the foregoing amendments, Claims 1 through 6 were pending in this application. Claims 1 and 6 have been amended herein, and new claims 7 through 68 have been added.

In the Office Action, Claims 1 through 2 and 6 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Application No. 2004/0082963 to Gannoe et al. Applicants' invention date predates the October 23, 2002 filing date of Gannoe, and Applicants therefore believe that Gannoe can be removed as a reference. However, Applicants also believe that independent Claim 1 as currently amended is patentably distinct from the disclosure in Gannoe, and believe that the currently pending claims are patentable on that basis.

In particular, at least the following limitation from Claim 1 is nowhere disclosed or suggested in Gannoe:

An artificial stoma device sized and configured to be installed in an esophagus or stomach of the patient.

Gannoe fails to disclose an implantable stoma device. To the contrary, Gannoe discloses a device for acquiring tissue folds or plications in a circumferential configuration within a hollow body organ, such as to create a pouch or partition. See, e.g., Gannoe Abstract. In connection with the Figures referenced by the Examiner, the device is utilized transesophageally, "thereby creating a tissue ring (TR) around the circumference of the fastened tissue." See paragraph 33. The effect is to create a tissue stoma. As cautioned by Gannoe (paragraph 34):

Once the tissue 111 has been fastened or fixed, the tissue acquisition device 105 is then removed. In doing so, the inner portion distal end 110 of the device may be carefully pulled

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through the newly created tissue ring or stoma created by the procedure so as to minimize stretching of the ring or stoma.

Thus, contrary to teaching the implantation of a stoma device, Gannoe teaches the *in situ* formation of a stoma by manipulating native tissue.

Nor does the Gannoe reference disclose the following second limitation of Claim 1:

A gastrointestinal sleeve connected to the artificial stoma device.

Since the teaching of Gannoe lacks an artificial stoma device as that term is utilized in Applicants' claimed invention, the bypass conduit 113 cannot be connected to the stoma device. Attachment of the bypass conduit 113 is described by Gannoe as follows (paragraph 35):

Such a bypass conduit 113...may be secured to the newly created tissue ring (TR) or stoma (ST) endoscopically using a clip or stent like structure at the anchored end to produce an interference fit within the stoma. Alternatively, the bypass conduit could be placed over the acquisition device of the present invention, and secured by the same fastening elements, and at the same time as the formation of the stoma.

Accordingly, Gannoe fails to disclose connection of the gastrointestinal sleeve to the artificial stoma device.

At least the following third limitation of Applicants' amended Claim 1 is nowhere disclosed or suggested in Gannoe:

A non-tissue cuff on the stoma device to secure the stoma device at an installation site.

As recited above, Gannoe fails to disclose an artificial stoma device, and necessarily therefore fails to disclose Applicants' claimed structure in which the artificial stoma device is

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provided with a non-tissue attachment cuff. The formed *in situ* stoma of Gannoe is inherently secured at its formation site without the implantation of a cuff.

In view of the foregoing, Applicants respectfully submit that independent Claim 1 is patentably distinct from the prior art of record, and withdrawal of the outstanding rejection is respectfully requested.

Original Claims 2 through 6 and new Claims 7 through 23 all depend upon Claim 1, and are believed to be patentable over the prior art for at least that reason. New Claims 7 through 23 have been added without the addition of any new matter.

Original dependent Claim 6 was erroneously labeled "Claim 5", giving rise to the Examiners' objection under 37 C.F.R. § 1.126. That numbering anomaly has been corrected in the foregoing amendments, and the objection is believed at this point to be moot.

The Applicants acknowledge with appreciation the Examiner's indication of allowability of dependent Claim 5. New independent Claim 24 is a combination of original independent Claim 1 and original dependent Claim 5. New dependent Claims 25 through 28 correspond to original dependent Claims 2 through 4 and 6. Accordingly, Applicants respectfully submit that new Claims 24 through 28 are in condition for allowance.

New independent Claim 29 is believed to be allowable for similar reasons to those underlying the allowability of original Claim 5. New dependent Claims 30 through 49 correspond to current Claims 2 through 4, 6 through 11 and 13 through 23. New dependent Claims 30 through 49 are therefore believed to be allowable for at least the foregoing reasons.

New independent Claim 50 relates to a difference between Applicants' attachment structure and the tissue ring disclosed by Gannoe et al., which was discussed at the interview. In particular, Gannoe discloses forming a circumferential tissue plication, in which an interior lining of the stomach is pinched or drawn by suction to form a radially inwardly projecting extension, and then fastened in that form to create a tissue ring. See, for example, Figure 5d or any of the anatomical drawings in Gannoe.

Claim 50 is directed to Applicants' structure for attaching Applicants' apparatus in a manner that does not require a tissue plication. Applicants' contrary method of attachment leaves the configuration of the native tissue as undisturbed as possible, and instead involves placement of a highly flexible attachment cuff adjacent the interior wall (mucosal surface of the stomach) at the attachment site, and advancing an anchor through the wall to the outside (serosal) surface of

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the stomach to enable positioning of an anchor against the serosal surface. Applicants respectfully submit that neither this structure nor the related methodology is disclosed or suggested in Gannoe.

Dependent Claims 51 through 68 relate to various additional structural features.

Applicants believe that no new matter has been added by the foregoing amendments. As requested by Examiner Jackson at the interview, the following table includes citations to Applicants' specification and claims as filed for support under 35 U.S.C. § 112 first paragraph for the new claims. Inclusion of a particular citation herein does not suggest or imply that additional §112 first paragraph support may not be found elsewhere in Applicants' specification as filed.

New Claim	Written Description Support
7	Page 20 lines 8-9
8	Page 20 lines 9-11
9	Page 32 lines 10-12
10	Page 21 lines 5-6
11	Page 21 lines 6-8
12	Page 21 lines 17-19
13	Page 21 lines 17-20
14	Page 24 line 18
15	Page 24 lines 21-24
16	Page 24 lines 26-29
17	Page 25 lines 17-18
18	Page 27 line 20
19	Original Claim 6
20	Page 31 line 19
21	Page 33 lines 8-10
22	Page 35 line 19

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New Claim	Written Description Support
23	Page 36 lines 25-26
24	Original Claims 1 and 5
25	Original Claim 2
26	Original Claim 3
27	Original Claim 4
28	Original Claim 6
29	Original Claims 1 and 5; Page 21 lines 17-19
30	Original Claim 2
31	Page 25 lines 11-12
32	Original Claim 4
33	Original Claim 6
34	Page 20 lines 8-9
35	Page 20 lines 9-11
36	Page 32 lines 10-12
37	Page 21 lines 5-6
38	Page 21 lines 6-8
39	Page 21 lines 17-20
40	Page 24 line 18
41	Page 24 lines 21-24
42	Page 24 lines 26-29
43	Page 25 lines 17-18
44	Page 27 line 20
45	Page 28 lines 9-26
46	Page 31 line 19
47	Page 33 lines 8-10
48	Page 35 line 19
49	Page 36 lines 25-26
50	Original Claim 1; Page 24 line 18; Page 28 lines 9-26

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New Claim	Written Description Support
51	Page 27 line 20
52	Original Claim 3
53	Original Claim 4
54	Page 28 lines 12-14
55	Page 28 lines 12-18
56	Page 28 line 16
57	Page 20 lines 8-9
58	Page 20 lines 9-11
59	Page 32 lines 10-12
60	Page 21 lines 5-6
61	Page 21 lines 6-8
62	Page 21 lines 17-20
63	Page 24 lines 18
64	Page 24 lines 21-24
65	Page 24 lines 26-29
66	Page 33 lines 8-10
67	Page 35 line 19
68	Page 36 lines 25-26

### CONCLUSION

In view of the foregoing, Applicant respectfully submits that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 3/11/05

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